



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION III  
1650 Arch Street  
Philadelphia, Pennsylvania 19103-2029

**VIA UPS**

SEP 16 2015

Diane B. Dona, Director of Safety and Environment  
Merck Sharp & Dohme Corporation  
770 Sumneytown Pike  
West Point, PA 19486

**Re: Notice of Violation  
Compliance Evaluation Inspection  
June 24, 2015  
EPA ID No. PAD002387926**

**Docket Number: R3-15-NOV-RCRA-042**

Dear Ms. Dona,

On June 24, 2015, the U.S. Environmental Protection Agency, Region III ("EPA") conducted a Compliance Evaluation Inspection ("CEI") under the Pennsylvania Solid Waste Management Act ("SWMA"), as amended, 35 P.S. §§6018.101 - 6018.1003, and the Resource Conservation and Recovery Act ("RCRA"), as amended, 42 U.S.C. Sections 6901 et seq. of your facility. Based on the inspection and/or review of pertinent information, EPA has determined that Merck Sharp & Dohme Corporation ("Merck" or "the Facility") was in violation of regulations promulgated under RCRA. As a result of this finding, the Agency is issuing this **Notice of Violation ("NOV")**. The specific violations are as follows:

1. The inspector observed two (2) 1-gallon hazardous waste containers on a 90-day Hazardous Waste Accumulation Area (90-day Pad) that at the time of the inspection did not have start accumulation dates on them. According to 25 PA 262a [40 CFR 262.34(a)(2)], the date upon which accumulations begins must be clearly marked and visible for inspection on each hazardous waste container.
2. The inspector observed a piece of equipment ("wand") used to transfer hazardous waste from tank TA-9400 to a drum. That wand did not meet BB requirements. At the time of the inspection, the wand used in this process had an open end that was not

secured by a second valve or a cap. According to 25 PA 265a [40 CFR 265.1056], open-ended lines must be equipped with a cap, blind flange, plug, or a second valve that should seal the open end at all times except during operations that require the hazardous waste stream to flow through the line.

3. At the time of the inspection, the inspector observed two (2) points subject to monitoring that were not tagged as being a part of the Facility's monitoring program. These points included: (i) the valve at the end of the flexible hose coming off of tank TA-9400, and (ii) the valve present at the base of the filling wand. According to 25 PA 265a [40 CFR 265.1050(c)], each piece of equipment subject to [40 CFR Subpart BB] must be marked in a manner that it can be distinguished readily from other pieces of equipment. In addition, these points must follow monitoring requirements outlined in [40 CFR 265.1057].

A copy of the Inspection Report, documenting the findings of the inspector, is enclosed for your information.

Based on documents sent by Merck to the EPA and correspondence conducted between the two, there is no response required to this NOV at this time.

Section 3008(a) of RCRA authorizes EPA to take an enforcement action whenever it is determined that any person has violated or is in violation of any requirement of RCRA as amended. Such an action could include a penalty of up to \$37,500 per day of violation. In addition, failure to achieve and maintain compliance with the regulations cited in the NOV may be treated as a repeated offense and can constitute a "knowing" violation of Federal Law.

With regard to the Small Business Regulatory Enforcement and Fairness Act (SBREFA), please see the "Information for Small Businesses" memo, enclosed, which might be applicable to your company. This enclosure provides information on contacting the SBREFA Ombudsman to comment on federal enforcement and compliance activities and also provides information on compliance assistance. As noted in the enclosure, any decision to participate in such program or to seek compliance assistance does not relieve you of your obligation to respond in a timely manner to an EPA request or other enforcement action, create any rights of defenses under law, and will not affect EPA's decision to pursue this enforcement action. To preserve your legal rights, you must comply with all rules governing the administrative enforcement process. The Ombudsman and fairness boards do not participate in the resolution of EPA's enforcement action. EPA has not made a determination as to whether or not Merck is covered by SBREFA.

This NOV is not intended to address all past violations, nor does it preclude EPA from including any ongoing, including the ones cited in this letter, or past violations in any future enforcement action. Any response to this NOV shall be addressed to:

Rebecca Serfass  
U.S. Environmental Protection Agency – Region III  
RCRA Office of Land Enforcement (3LC70)  
1650 Arch Street  
Philadelphia, PA 19103  
[Serfass.Rebecca@epa.gov](mailto:Serfass.Rebecca@epa.gov)  
(p): 215-814-2047



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Carol Amend, Associate Director  
Land and Chemicals Division  
Office of Land Enforcement

Date: *Sept 16, 2015*

Enclosure

cc: M. Gross, PADEP, w/o enc.  
P. Belgovane, 3LC70, w/o enc.  
R. Serfass, 3LC70, w/o enc.